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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,408	12/26/2001	Larry Caldwell	CALD-005	3760

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EXAMINER	
OH, SIMON J	
ART UNIT	PAPER NUMBER
1618	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/029,408	CALDWELL ET AL.	
	Examiner	Art Unit	
	Simon J. Oh	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's amendment, response, petition for extension of time, information disclosure statement, and affidavit under 37 C.F.R. 1.132, all received on 21 November 2006.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 21 November 2006 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claim 32 under 35 U.S.C. 112, second paragraph, as being indefinite is hereby withdrawn in view of the present amendment to that claim.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1-18 and 24-33 under 35 U.S.C. 103(a) as being unpatentable over Petrus in view of Edwards and Biedermann *et al.* is maintained.

The rejection of Claims 19-23 under 35 U.S.C. 103(a) as being unpatentable over Petrus in view of Edwards, Biedermann *et al.*, and Shudo *et al.* is maintained.

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Petrus (U.S. Patent No. 6,399,093) in view of Edwards (U.S. Patent No. 5,989,559)

The Petrus patent teaches compositions for the treatment of musculoskeletal disorders, which includes carpal tunnel syndrome (See Abstract; and Column 1, Lines 26-44). Among the suitable active ingredients disclosed are non-steroidal anti-inflammatory agents, such as indomethacin, diclofenac, ibuprofen and ketoprofen (See Column 4, Table 1). The disclosed compositions may be formulated into various dosage forms, including creams and films (See Column 3, Lines 18-25). Such compositions are suitable for treating humans afflicted with musculoskeletal disorders (See Column 13, Examples 3 and 4). Non-steroidal anti-inflammatory agents are typically present in the disclosed formulations in amounts of 5% by weight (See Examples).

The Petrus patent does not explicitly disclose the treatment of carpal tunnel syndrome by applying a topical formulation to a palmar dermal surface proximal to the carpal tunnel.

The Edwards patent is used here as a teaching reference to show that it is commonly known in the prior art to apply topical medication on or near the loci of sites of pain, such as those caused by carpal tunnel syndrome (See Examples L, N, O, P, and Q).

It would be obvious to one of ordinary skill in the art at the time the instantly claimed invention was made to combine the disclosures of the prior art into the objects of the instantly claimed invention. As the Edwards patent demonstrates, the placement of topical medication on or.near the loci of sites of pain, such as those caused by carpal tunnel syndrome, is commonly known by one of ordinary skill in the art, and is therefore obvious. As the Petrus and Edwards patents deal with the treatment of pain, the references are considered to be analogous. Thus, one of ordinary skill in the art has a reasonable expectation of success in applying the teachings of the Edwards patent to those of Petrus. The examiner finds no novelty claim limitations dealing with the specific placement of NSAID formulations on a subject and shifts the burden onto the applicant to demonstrate how the instantly claimed invention shows unexpected results from what is known in the prior art. It is the position of the examiner that topical forms disclosed in the prior art such as films sufficiently read on the instantly claimed invention so as to make the use of patches in treatment obvious to one of ordinary skill in the art.

Response to Arguments

Applicant's arguments filed 21 November 2006 have been fully considered but they are not persuasive. The examiner has considered the affidavit submitted under 37 C.F.R. 1.132, but it is not considered to be persuasive.

The examiner appreciates the applicant's efforts to establish what a reasonably skilled practitioner in the art knows. In the affidavit, three main points are made:

1) It is well known in the art that just because an active agent is administered orally to treat a medical condition, it does not mean that it can be effective when administered topically to treat

the same of different medical condition.

2) It is well known in the art that just because an active agent is administered topically to treat one condition, it does not mean that it can be effective when topically administered to treat other conditions.

3) Because of the location of the target nerves that are responsible for carpal tunnel syndrome, it was not at all certain that the claimed methods would work prior to the actual reduction to practice reported in the instant application.

In regard the first point that is made, the examiner does not see how this is relevant to the issues in this case. The Petrus reference clearly discloses the topical administration of non-steroidal anti-inflammatory drugs.

In regard to the second point, what is meant by the phrase "other conditions" is something that has been a source of contention in the prosecution of this case. Specifically, even though the prior art teaches that the methods and compositions disclosed therein are useful for treating pain, the question is raised of whether or not pain of a different pathology constitutes an entirely different type of condition such that those prior art methods and compositions would not have a reasonable expectation of success in treating the those types of pain of differing pathologies. In the view of the examiner, there would be a reasonable expectation of such success, which will be further explained below.

In regard to the third point, the examiner does not find this persuasive. In the analysis of claims under obviousness, one of ordinary skill in the art need only have a reasonable expectation of success. Very few things in science are ever "at all certain", for there are usually variables that are not consciously accounted-for which may affect the outcome of a particular

course of treatment. The use of penetration enhancers are known in the topical administration art, and it seems logical to administer a topical composition closer to the site of pain rather than at a more remote site on the body.

A primary issue that remains unresolved in this case is whether or not pain of a different pathology constitutes an entirely different type of condition such that those prior art methods and compositions would not have a reasonable expectation of success in treating the those types of pain of differing pathologies. Given that the prior art already discloses the topical administration of non-steroidal anti-inflammatory drugs for the treatment of pain where the drug is to be administered at a location proximal to the site of pain, and further that the pharmacological action of the drug on the patient is presumably not any different between prior art methods and the instantly claimed methods, then it is the position of the examiner that no patentable distinction has been shown between types of pain that differ in their particular pathologies. Therefore, the claims remain rejected over the prior art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Simon J. Oh
Examiner
Art Unit 1618

sjo

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER